

TERMS AND CONDITIONS FOR SUPPLY OF GOODS AND/OR SERVICES

(Revised February 2, 2024)

1. DEFINITIONS

- 1.1 **"MSD"** shall mean **Merck Sharp & Dohme s.r.o.**, a company with its registered office in in Praha 5, Na Valentince 3336/4, ZIP code 150 00, corporate identification number 284 62 564, registered in the Commercial Register maintained by the Municipal Court in Prague, , Section C, Insert 143294
- 1.2 The **"Supplier"** shall mean the legal or natural person supplying the Works to MSD.
- 1.3 MSD and the Supplier shall together be referred to as the **"Parties"** and each individually as a **"Party"**.
- 1.4 The **"Agreement"** shall mean the contract between MSD and the Supplier, incorporating these terms and conditions and, where appropriate, MSD's purchase order and any other document referred to in MSD's purchase order.
- 1.5 The **"Works"** shall mean all the work, goods, services, materials, parts, components, plant, equipment, insurance, transport and all other things which the Supplier is required to provide in order to fulfil its obligations under the Agreement and Works shall be construed as any one or more of the above as appropriate.
- 1.6 The **"Contract Price"** shall mean the price to be paid for the Works by MSD.
- 1.7 An **"Authorised Signatory"** is a representative of a Party who has authority by virtue of law to commit that Party to a legally binding contract.
- 1.8 **"Good Practice"** shall mean exercising the same skill, expertise and judgment and using facilities and resources of a similar or superior quality as might be expected from a person who:
- (a) is skilled and experienced in providing the Works; and
 - (b) takes all proper and reasonable care and is diligent in performing his/her obligations.
- 1.9 A **"Health Professional"** is defined as being any member of the medical, dental, pharmacy, and nursing professions and any other persons, including administrative staff, who in the course of their professional activities may administer, prescribe, purchase, recommend, or supply a medicine.
- 1.10 A **"Transfer of Value"** is defined as any direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise.

2. INTRODUCTION

- 2.1 The Agreement applies to and supersedes any terms and conditions oral or written referred to, offered or relied on by the Supplier, whether in negotiation or at any other time in the dealing between MSD and the Supplier, with reference to the Works.
- 2.2 Without prejudice to the matters above, MSD will not be bound by any standard, oral, or printed terms or any other terms whatsoever provided by the Supplier in any of its documents or otherwise unless the Supplier specifically states in writing, separately and distinct from such terms that it intends such terms to apply and MSD by an Authorised Signatory confirms its acceptance in writing to the Supplier.

3. ENTIRE AGREEMENT

- 3.1 The Agreement cannot be varied except in writing and as agreed and by an Authorised Signatory of both Parties. The Agreement encompasses the whole agreement reached between the Parties.
- 3.2 Each Party agrees that it has not relied on and shall have no remedies in respect of any representations or warranties (whether made innocently or negligently) that is not set out in the Agreement. Each Party agrees that its only liability in respect of those representations and warranties that are set out in the Agreement (whether made innocently or negligently) shall be for breach of contract.
- 3.3 Nothing in this Clause 3 is intended to exclude liability for fraud.

4. WAIVER

- 4.1 No single nor repeated waiver for any period of time by either MSD or the Supplier of any of its rights hereunder shall prejudice its ability to enforce any other rights accrued or accruing under the Agreement.

5. SPECIFICATION, DESCRIPTION AND SAMPLE

- 5.1 The Works shall be in conformity with the specifications, drawings, samples or any other description or descriptions of the Works agreed between the Parties.
- 5.2 It shall be a condition of sale that the Supplier has the right to sell the goods, that the goods are free from any third party encumbrance, that MSD shall enjoy quiet possession of the goods and, without affecting the generality of the foregoing, that MSD shall have the right to use the goods for any purpose of which the Supplier is, or should be reasonably aware without interference from any third party on the grounds of infringement of any rights in industrial property.

6. PROVISION AND QUALITY OF THE WORKS

- 6.1 To the extent that the Works comprise goods, they shall be of merchantable quality and free from defects in material or workmanship.
- 6.2 The Supplier will provide the Works to MSD in accordance with Good Practice and in accordance with all applicable laws, regulations, orders, governmental requirements and industry guidelines.
- 6.3 The Supplier warrants to MSD that it has sufficient resources, staff, experience and expertise to carry out the Works to the required standard and that it will take all proper and reasonable care and will be diligent in performing its obligations under the Agreement.
- 6.4 MSD may at all reasonable times during manufacture, inspect on the Supplier's premises, the manufacture and workmanship of all goods to be supplied by the Supplier, and, if any item is being manufactured on other premises, the Supplier shall obtain for MSD permission to inspect and shall give to MSD reasonable notice of the dates on and the place which the goods will be ready for testing and shall, at the Supplier's own cost give MSD all assistance (by supply of labour, materials and power or otherwise) as may be reasonably necessary to carry out the inspection and/or testing effectively. Such inspection or testing shall not relieve the Supplier from his obligations under the Agreement.
- 6.5 No change shall be made to the method of manufacture or ingredients used, compared with agreed material without giving prior written notice to MSD, and without obtaining MSD's prior written approval.

7. FITNESS FOR PURPOSE

- 7.1 The Works shall be fit and sufficient for the purpose(s) for which they were intended as were expressly made known to the Supplier or could reasonably have been inferred by it.

8. QUALITY ASSURANCE AND GOOD MANUFACTURING PRACTICE

- 8.1 The Supplier shall, where applicable, comply with the principles and guidelines of Good Manufacturing Practice (GMP) set out in Commission Directive 2003/94/EC (implemented by the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended.
- 8.2 The Supplier shall ensure that all personnel employed by it to perform the Works shall have received and shall continue to receive appropriate training by qualified persons in the theory and application of the concept of quality assurance and GMP (if applicable) and in the provision of calibration and maintenance services and shall have the necessary qualifications and practical experience in the provision of such services. Upon request, the Supplier shall provide MSD with appropriate evidence of the Supplier's compliance with this sub clause.
- 8.3 The Supplier shall immediately notify MSD if at any time its ČIA (Český institut pro akreditaci, o.p.s.)/other accreditation (where applicable) is withdrawn or suspended and any such withdrawal or suspension shall entitle MSD to terminate the Agreement forthwith.

9. CHANGE OF PERSONNEL

- 9.1 The Supplier is responsible for maintaining reasonable continuity in personnel providing the Works on its behalf, but reserves the right to make changes from time to time. Where substitution of personnel occurs:
- (a) no additional charge will be made for any handover period, and the Supplier remains responsible for Works performed by any individual on its behalf;
 - (b) where the Supplier's charges are on a time and materials basis, it is the Supplier's responsibility to ensure that the relevant skills and experience of any replacement personnel remain commensurate with the fee rates charged;
 - (c) the terms of the Agreement and in particular (but not limited to) the Contract Price and timetable of the project, will remain unchanged, unless otherwise agreed by the Parties in writing;
 - (d) the Supplier shall ensure that any substitute personnel shall have the necessary qualifications and experience to fulfil the obligations pursuant to the Agreement; and
 - (e) the Supplier acknowledges that MSD has the right to refuse the acceptance of the substitute personnel in the event of non-compliance with this clause.
- 9.2 In the event that the Supplier cannot provide either the original personnel or acceptable substitute personnel, MSD is entitled to terminate the Agreement immediately.

10. PRICE

- 10.1 The Contract Price shall be a fixed price unless otherwise agreed in writing between the Parties.
- 10.2 The Contract Price shall not be increased by the Supplier (whether following an increase in the cost of labour or materials or otherwise) unless MSD, at its absolute discretion, expressly agrees in writing in advance to such increase.

- 10.3 In addition to the Contract Price, the Supplier may charge MSD for agreed expenses providing such expenses are:
- (a) reasonably and properly incurred by or on behalf of the Supplier;
 - (b) invoiced by the Supplier at cost; and
 - (c) the Supplier obtains MSD's written approval before incurring any such costs or expenses. Invoices issued by the Supplier to MSD covering reimbursement of expenses must be accompanied by relevant receipts.
- 10.4 Further to the provisions of Clause 10.3(c), the Supplier agrees to provide and will procure that any third party agency it may work with provides, in the performance of its obligations under these terms, copies of all expenses and pass-through costs related to air travel, local transportation, hotel accommodation, meals, catering and any other travel or hospitality related costs or expenses. The Supplier shall maintain and shall procure that the third parties it works with so maintain all records in accordance with generally acceptable accounting practices.
- 10.5 The Supplier agrees that payment of pass-through costs and expenses submitted for payment without the required information and copies of pass-through costs may be withheld or delayed until the required information has been provided.
- 10.6 The Supplier agrees that for purposes of the Agreement, and its collaboration with MSD, that MSD will handle all contractual arrangements with Health Professionals. To this end, neither Supplier nor any of its third party contractors, will contract with any Health Professional for any Transfer of Value.

11. PAYMENT

- 11.1 Payment for the Works and agreed expenses shall be made in arrears against an agreed invoice submitted by the Supplier. Unless agreed otherwise by the Parties in writing, payment for the Works will be made by MSD within 90 days after the date of receipt of the invoice in question.
- 11.2 All invoices must contain the following information:
- (a) the amount due, net of Value Added Tax (VAT);
 - (b) the amount of VAT payable;
 - (c) the rate of VAT chargeable;
 - (d) any further information required to ensure the invoice is a valid VAT invoice;
 - (e) a valid purchase order number issued by MSD;
 - (f) itemised receipts and copies of pass through costs as set out in Clause 10.4, and
 - (g) the name of the Supplier's contact at MSD.
- 11.3 MSD will be entitled to return any invoice and withhold payment of the Contract Price and/or any other amounts charged by the Supplier to MSD until an invoice complying with the requirements of this clause is presented to it.
- 11.4 The Supplier may charge statutory interest on unpaid amounts from the due date of payment of a valid invoice (provided that such invoice complies with the requirements of this clause). The payment of interest on unpaid amounts does not affect MSD's right to any compensation of damage.

12. DELIVERY

- 12.1 As appropriate, the Works must be delivered carriage paid to such destination as MSD may direct in MSD's order. Where applicable, delivery shall be subject to any special conditions or requirements agreed between the Parties. If the Works are incorrectly completed the Supplier shall be liable for any additional expense incurred in delivering them to their correct destination.
- 12.2 MSD may postpone delivery by informing the Supplier at any time before delivery.

13. PROPERTY AND RISK

- 13.1 Subject to the express provisions of clause 13.2 below, the property and risk in the Works shall remain with the Supplier until they are completed and accepted by MSD as specified in the Agreement.
- 13.2 If the Agreement provides for payment by MSD of part of the agreed Contract Price at any time before any work hereunder is commenced by the Supplier and/or if MSD pays for the Works or materials being prepared, procured, manufactured, assembled or produced by any means whatsoever whether at the premises of MSD, Supplier or any sub-Supplier or elsewhere and/or if MSD pays part of the agreed Contract Price at various times or stages during the Agreement (whether such payments are made in advance or arrears of given stages in the fulfilment of the Agreement) then such payments are to be regarded as part payments and not deposits of the agreed Contract Price and the property in these Works and materials shall pass to MSD upon making the first agreed payment.
- 13.3 Insofar as the property in the Works and materials as set out in clause 13.2 pass to MSD upon making the agreed payment, the risk in these goods and materials shall remain with the Supplier until the Works are completed and accepted as specified in the Agreement.

14. TIME

- 14.1 The date of completion of the Works shall be agreed in writing between MSD and the Supplier or where appropriate, specified in MSD's purchase order. The Supplier shall furnish such programmes of manufacture, delivery and completion as MSD may reasonably require and the Supplier shall give notice in writing to MSD as soon as is practicable if such programmes are, or are likely to be, delayed.

15. INTELLECTUAL PROPERTY RIGHTS

- 15.1 Subject to clause 15.2 below the Supplier warrants and represents that the Supplier has the right to use the relevant intellectual property rights in the Works for the Agreement and that the Works will not infringe intellectual property rights of third parties.
- 15.2 Title to and ownership of the Works and any related trademark, copyright or any other intellectual property rights arising out of the Works shall remain the exclusive property of MSD. The Supplier hereby agrees to assign all such intellectual property rights to MSD absolutely and to execute all documents required to give effect to this intention. For the avoidance of doubt, any such intellectual property rights which belonged to either Party or any third party hereto prior to the commencement of the Agreement shall remain the property of that party. The Supplier hereby irrevocably grants to MSD for the duration of the Agreement, all licences and permissions, express or implied, necessary for the operation of the Agreement.

16. PUBLICITY

- 16.1 The Supplier agrees not to use or reference in any advertising, press release, interview,

presentation to prospective clients, article, promotional material, or other communication, MSD's company or representative name, endorsement, direct or indirect quote, code, drawing, logo, trademark, specification, picture, or deliverables arising out of the Works without the prior written consent of MSD, which consent may be withheld at its absolute discretion.

17. INSURANCE

- 17.1 During the term of the Agreement and for a period of not less than five years thereafter the Supplier shall have in place insurance cover for such risks and for such amounts as a reasonable insurance broker advising a business providing the Works to MSD would consider prudent. Unless otherwise agreed in writing by MSD, this insurance cover shall include, but not be limited to Product Liability, Business Interruptions Liability and Professional Liability. The Supplier shall notify MSD in writing of any changes in the insurance coverage (including without limitation cancellation, non-renewal or material modification of the policy) within three (3) working days after the change takes place.
- 17.2 The Supplier shall deliver to MSD, within seven days of the commencement of the Agreement and on request during the Agreement, Certificates of Insurance as evidence that policies providing such coverage and limits of insurance are in full force and effect and with insurers with an AM Best rating of A- or better. The Supplier shall provide not less than thirty (30) calendar days advance notice in writing to MSD of any cancellation, termination, or material alteration of said insurance policies.
- 17.3 The Supplier's obligations under clause 17.1 shall survive the termination of the Agreement.

18. CONTINGENCY PLANNING

- 18.1 Throughout the term of the Agreement the Supplier must have in place reasonable contingency and disaster planning arrangements designed to minimise any interruption or disruption to the provision of the Works including interruptions and disruptions caused by the loss, damage or destruction of any premises, equipment, infrastructure or records.
- 18.2 The contingency and disaster planning arrangements referred to in clause 18.1 must be reasonably satisfactory to MSD and MSD and its representatives may inspect and take copies of the information referred to in clause 18.1 upon giving 5 (five) days notice.

19. RECORDS

- 19.1 The Supplier must keep clear, accurate, complete and up to date records and information relating to:
- (a) all matters relating to the Works and their performance for which records must be kept under the applicable laws; and
 - (b) the performance of its obligations under the Agreement including appropriately detailed information regarding all enquiries, claims, settlements, payments, compensation, and systems processes.
- 19.2 The Supplier shall keep and retain the records and information referred to in this clause to the same standards as would be required of a reasonable person providing the Works.
- 19.3 The Supplier must on reasonable notice from MSD, make available to MSD and its representatives any records and information belonging to the Supplier and/or any third party involved in the provision of the Works which may be relevant in confirming:
- (a) the Supplier's compliance with its obligations under the Agreement; or

(b) the calculation of any sums payable by the Supplier under the Agreement.

19.4 The Supplier must on request give MSD, its representatives and any applicable regulatory agency access to the Supplier's premises and records (and/or those of any third parties involved in the provision of the Works) for the purpose of any inspection or investigation requested or required by the regulatory agency relating to the Works.

19.5 The Supplier must ensure that its staff and the staff of any third party involved in the provision of the Works are (in so far as it is reasonable) made available to assist MSD in the exercise of its rights under Clauses 19.3 and 19.4.

20. FORCE MAJEURE

20.1 Neither Party shall be liable to the other Party for any failure to fulfil its obligations under the Agreement if such a failure is caused by circumstances beyond its reasonable control in which event the obligations of the failing Party shall be suspended for the period during which such force majeure operates, provided that reasonable efforts have nonetheless been made by them to fulfil their obligations under the Agreement, and provided further that the suspended obligations are fulfilled as soon as possible after the force majeure ceases to so operate.

21. REJECTION

21.1 If any of the Works do not comply with any term of the Agreement in the reasonable opinion of MSD, including quantity, quality or description, or as appropriate with the purchase order, MSD shall be entitled to reject those Works at any time after delivery or completion irrespective of whether MSD has accepted them or made payment for them.

21.2 Any acceptance of such Works by MSD shall be without prejudice to any rights that MSD may have against the Supplier, including but not limited to those set out in clause 21.3.

21.3 In the event of rejection of Works under clause 21.1, MSD may at its absolute discretion;

(a) seek recovery of sums paid to the Supplier in respect of the rejected Works as a debt; or

(b) seek alternative Works from the Supplier which alternative shall in all respects comply with the terms of clauses 5, 6 and 7 hereof, or

(c) replace the rejected Works with works carried out by another in accordance with the Agreement as near as practicable to the same specifications as circumstances shall permit. As appropriate, MSD shall be entitled to return any rejected Works, carriage forward, to the Supplier at the risk of the Supplier.

21.4 Without prejudice to any other remedy which MSD has against the Supplier, any defective parts, materials or workmanship which shall appear within a period of twelve months (or any other period agreed in the Agreement) following acceptance of the Works shall be replaced or made good by the Supplier at his own expense within a reasonable time of written requirement of such by MSD.

21.5 Nothing in clauses 21, 22 and 23 shall prejudice the right of MSD to enforce any remedy at law which it may have against the Supplier for breach of the Agreement.

21.6 MSD reserves the right to cancel the Works on account of late delivery.

22. NON-DELIVERY

22.1 If the Supplier does not complete the Works or any part thereof within the time specified in

MSD's purchase order, MSD shall be entitled to terminate the Agreement forthwith, complete the Works to the same or similar description to make good such default and recover from the Supplier the amount by which the cost of obtaining such replacement Works exceeds the price which would have been payable to the Supplier in respect of the Works so replaced without prejudice to any other remedy at law.

23. LIABILITY AND INDEMNITY

- 23.1 To the fullest extent permissible by law, MSD shall not be liable for loss of revenue, business contract, anticipated savings, profits, data or information, damage to property, or any indirect or consequential loss howsoever arising whether from negligence, breach of contract or otherwise, except that the limitation set out in this clause 23.1 shall not apply to the profit element in the Contract Price.
- 23.2 Nothing in the Agreement shall limit or exclude the liability of MSD for:
- (a) death or personal injury resulting from negligence; or
 - (b) fraud or fraudulent misrepresentation; or
 - (c) any matter which it would be illegal for MSD to exclude or attempt to exclude its liability.
- 23.3 The Supplier shall indemnify MSD against all liabilities, costs, expenses, damages and losses (including legal fees and expenses) incurred by MSD arising out of or in connection with:
- (a) any claim made against MSD for actual or alleged infringement of a third party's intellectual property rights or other rights arising out of, or in connection with, the supply or use of the Works; and
 - (b) any claim made against MSD by a third party arising out of, or in connection with, the supply of the Works, to the extent that such claim arises out of the breach, negligent performance or failure or delay in performance of the Agreement by the Supplier, its agents or subcontractors.

24. TERMINATION

- 24.1 MSD may terminate the Agreement at any time on giving thirty (30) days written notice to the Supplier.
- 24.2 If the Supplier ceases to conduct business in the normal course, becomes insolvent or subject to insolvency proceedings MSD may terminate the Agreement with immediate effect and shall be entitled to the immediate return of any funds advanced as part payment under clause 13.2 above. Such funds shall be returned to MSD unencumbered and without any charge or other lien attaching to it.
- 24.3 Should the Supplier cease to conduct business in the normal course and/or in any of the circumstances as set out in Clause 24.2 the ownership and copyright and any other proprietary rights including but not limited to of any computer program(s) and the relevant source code and any other ancillary code pertinent to the usual use of the program(s) and any other propriety right associated with the program(s) in which MSD has an interest arising out of the Agreement shall vest absolutely in MSD forthwith. The Supplier undertakes to execute all necessary documents to give effect to the intention of this sub-clause.

25. CONSEQUENCES OF TERMINATION

- 25.1 Termination of the Agreement does not affect the accrued rights and liabilities of the Parties or

the enforceability of clauses 15, 16, 17, 19, 21, 23, 24, 25, 28 and any other provisions of the Agreement that are intended to remain in force after its termination.

- 25.2 Any licences that the Supplier has under the Agreement to use any intellectual property rights belonging to MSD or any of its group companies will immediately end when the Agreement is terminated and this shall include the Supplier's right to supply any products that use or are marked with that intellectual property.
- 25.3 Following the termination of the Agreement the Supplier must immediately return to MSD or destroy at MSD's request:
- (a) all the property in its possession or under its control that belongs to MSD and its group companies; and
 - (b) all copies of any materials and records of any kind that are in its possession or under its control (and in any medium) that contain any part of MSD's confidential information except that the Supplier may retain a copy of any confidential information that it reasonably requires for its accounting purposes or to comply with any applicable laws.
- 25.4 On termination of the Agreement for any reason MSD shall owe to the Supplier no further obligation other than to pay for such Works as have been properly completed or provided in accordance herewith. Partial payment for incomplete Works shall be at the absolute discretion of MSD.

26. PARTIAL INVALIDITY

- 26.1 If any provision or part of the Agreement is held to be invalid, it is to that extent to be deemed omitted from the Agreement and shall not affect the validity of the remaining terms and conditions of the Agreement which shall be interpreted as though the invalid clauses did not appear.

27. HEADINGS

- 27.1 The headings used in the Agreement are for convenience only and are not in any way intended to affect the construction of any clause, right or obligation contained in the Agreement.

28. CONFIDENTIALITY

- 28.1 In the course of Works done by the Supplier for MSD (i) arising out of (including negotiations of), and (ii) under the terms of the Agreement MSD may disclose to the Supplier certain confidential information which both Parties hereto acknowledge constitutes a valuable trade asset and a trade secret of MSD.
- 28.2 The Supplier, its employees, agents or sub-contractors will treat all such information as confidential, will not disclose any information to any third party without the prior written consent of MSD, and then only under terms no less restrictive than the terms contained in the Agreement and will take all reasonable steps to prevent any such disclosure. The Supplier undertakes not to use any information for the benefit of any third party.
- 28.3 The obligation of confidentiality set out here shall not apply to information which the Supplier is able to prove was already known to it and was not held subject to any duty of confidentiality, or to information which subsequent to disclosure by MSD comes into the public domain other than through breach of any duty of confidentiality or to information which is required to be disclosed pursuant to a legally enforceable order, direction or other regulation.
- 28.4 This duty of confidentiality shall survive any termination of the Agreement for a period of ten

(10) years from the date of termination.

- 28.5 If in the performance of duties under the Agreement the Supplier utilises any confidential information of MSD then the Supplier or any corporate body or person who becomes responsible for the obligations of the Supplier shall not sell, transfer or otherwise deal in any right which he/she may have in the Works without MSD's written consent (such consent not to be unreasonably withheld by MSD).

29. ASSIGNMENT AND SUB-CONTRACTING

- 29.1 For the avoidance of doubt, MSD shall be entitled to disclose any information obtained from the Supplier to its professional advisors and to a regulatory agency to the extent required or requested by such agency in connection with any regulatory filing, inspection or otherwise.
- 29.2 The Supplier shall not assign or sub-contract the whole or any part of the Agreement without the prior written consent of MSD. Notwithstanding any written agreed assignment or subcontract the Supplier shall be responsible for all work done and for all materials, goods and equipment supplied by him and by all subcontractors and assignees appointed by him.
- 29.3 The terms and conditions of the Agreement shall be binding upon, and shall inure to the benefit of, the Parties hereto and their respective successors and permitted assigns.

30. NOTICES

- 30.1 Any notice required to be served by either Party on the other shall be served at the addresses set out on MSD's purchase order or as otherwise notified by one Party to the other.

31. PROPER LAW AND FORUM

- 31.1 Both MSD and the Supplier agree that any dispute or question of interpretation arising out of the Agreement shall be decided in accordance with Czech law and shall be submitted to the exclusive jurisdiction of the courts of the Czech Republic.
- 31.2 Both MSD and the Supplier agree that the following Sections of the Act No 89/2012 Coll., Civil Code, as amended shall not be applicable to the Agreement: Section 1740(3); Section 1765; Section 1766; Section 1799 and Section 1800.
- 31.3 Both MSD and the Supplier agree that in compliance with the Section 1752 of the Civil Code, MSD shall have the right to unilaterally change these Terms and Conditions. In such a case, MSD shall send amended version of the Terms of Conditions to the registered office of the Supplier. The Supplier shall have the right to reject the amended version of the Terms and Conditions. In such a case of rejection, the Agreement shall be terminated by giving the termination notice with three (3) months notice period.

32. ETHICS/CONFLICT OF INTEREST

- 32.1 In its performance of the Agreement the Supplier shall adhere to business practices that are in accordance with the letter and spirit of applicable laws (including, but not limited to, the US Foreign Corrupt Practices Act 1977 and UK Bribery Act, 2010 and related legislation) and ethical principles as follows:
- (a) All transactions in connection with the Agreement shall be accurately reflected in the Supplier's records, and no funds or other assets shall be paid directly or indirectly to government officials, Health Professionals or persons acting on their behalf or to representatives of the other businesses for the purpose of influencing any decisions or actions with respect to MSD's business.

- (b) The Supplier shall conduct its activities hereunder so as to avoid loss or damage of MSD due to any real or apparent conflict of interest, and to require that all sub-contractors comply with such policy in connection with the Agreement.
- (c) MSD shall have the right to terminate the Agreement, without any penalty or obligation to pay damages, upon violation of the business practices mentioned in this clause by the Supplier, its employees, agents, representatives, sub-contractors or consultants.

32.2 MSD shall have the right to audit the books and records of the Supplier to ensure compliance with the Agreement and the Ethics Clause for the period of two (2) years following termination of the Agreement, and the Supplier shall provide its full cooperation and assistance in any such review conducted by MSD.

33. RELATIONSHIP BETWEEN THE PARTIES

33.1 The Supplier is engaged as and shall be at all times an independent contractor and the Supplier shall in no sense be considered an employee or an agent of MSD, and shall not therefore be able to bind MSD in any way nor be entitled or eligible to participate in any benefits, privileges or plans given or extracted by MSD to its employees.

33.2 The Supplier will not in any way bring into disrepute the business or reputation of MSD.

34. EXCLUDED ENTITIES

34.1 The Supplier represents and warrants that, as of the date of the Agreement, neither it, nor any of its officers, directors, Key Employees, or Key Sub-contractors has been in Violation. The Supplier shall notify MSD in writing immediately if any such Violation occurs or comes to its attention. If a Violation exists with respect to any of the Supplier's officers, directors, Key Employees, or Key Sub-contractors, the Supplier shall promptly remove such individual(s) or entities from performing any service, function or capacity related to the Works. MSD shall also have the right, in its sole discretion, to terminate the Agreement immediately in the event of any such Violation.

34.2 For the purposes of this clause:

- (a) A 'Key Employee' shall mean any employee of the Supplier who performs any work in connection with the Works.
- (b) A 'Key Sub-contractor' shall mean any individual or other entity which, as a subcontractor or agent of the Supplier, performs any work in connection with the Works.
- (c) 'Violation' shall mean that either the Supplier, or any of its officers, directors, Key Employees or Key Subcontractors has been:
 - (i) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General website, including 42 U.S.C. 1320a-7(a) (<http://oig.hhs.gov/fraud/exclusions/exclusionauthorities.html>);
 - (ii) identified in the List of Excluded Individuals/Entities (LEIE) database (<http://oig.hhs.gov/fraud/exclusions/listofexcluded.html>) on said website or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (<http://www.epls.gov>); or
 - (iii) listed by any US Federal agency as being suspended, debarred, excluded, or otherwise ineligible to participate in Federal procurement or non-procurement programs.

35. DATA PRIVACY AND SECURITY

- 35.1 The Parties will use personal data in accordance with any data protection legislation applicable to the Parties, in particular in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (hereinafter referred to as the "**Regulation**").
- 35.2 The Supplier represents and warrants that appropriate technical and organisational measures are in place to ensure that processing of personal data meets requirements of the Regulation and to prevent personal data breach and undertakes to implement and observe such measures including, as appropriate:
- i. the pseudonymisation and encryption of personal data;
 - ii. the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
 - iii. the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident; and
 - iv. a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.
- 35.3 The Supplier also undertakes to provide its full cooperation and assistance as required by MSD with handling of applications of data subjects exercising their rights.
- 35.4 The Supplier further undertakes to provide MSD with all information (including all necessary documentation, in particular regarding implemented technical and organizational measures for the protection of personal data) to demonstrate that the Supplier's obligations with respect to protection of personal data have been fulfilled, and to this end undertakes to allow MSD to perform audits, including inspections by MSD or an auditor assigned by the MSD; the Supplier shall provide its full cooperation and assistance in any such audit.
- 35.5 The Parties represent and warrant that in the event that either Party provides personal data to the other Party, including, without limitation, any individually identifiable health information, the Party providing the personal data represents and warrants that it has obtained all necessary consents, approvals and authorizations to provide the personal data to the receiving Party, and it is not violating the Regulation or any other laws, rules or regulations, or the rights of any individual or entity, by providing such personal data. Upon request by the receiving Party, the providing Party shall provide documentation of any applicable consents, approvals and authorizations.
- 35.6 No personal data, other than the personal data necessary for the Supplier to carry out the Works hereunder, shall be provided by the Supplier to MSD under the Agreement.
- 35.7 Data Integrity. Any documentation or data relevant to activities performed, including without limitation any GMP documentation, must be attributable, original, accurate, legible, complete, controlled, retrievable, and safe from intentional or unintentional manipulation or loss using appropriate technical and organizational measures. These items are required throughout the retention period of such data / documentation. The Supplier undertakes to process personal data received from MSD in connection with the Agreement only in the scope and for duration necessary for provision of the Works, such data shall be then, at the choice of MSD, promptly deleted or returned upon the termination of the Agreement, at the latest, unless required otherwise by applicable law.
- 35.8 The Parties agree that MSD will be entitled to recover from the Supplier any losses, damages, fines, costs, or expenses (including legal expenses and disbursements) incurred by MSD resulting from a personal data breach in relation to personal data processed by the Supplier in

connection with the Agreement and such amounts shall be deemed direct losses and not subject to any limitations or exclusions of liability (whether in the Agreement or otherwise).

36. MSD'S BUSINESS PARTNER CODE OF CONDUCT

- 36.1 MSD endeavors to hold itself and its Supplier to the highest ethical and compliance standards, including basic human rights, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. Without limiting any of the Supplier's other obligations hereunder, and without conflicting with or limiting any of the warranties, obligations or other provisions expressly set forth elsewhere in this Agreement, including without limitation its obligations hereof, the Supplier agrees that it will abide by the letter and spirit of MSD's Business Partner Code of Conduct (the "**Code**"), as in effect from time to time, a copy of which is available at <http://www.msd.com/about/how-we-operate/code-of-conduct/home.html>.
- 36.2 The Supplier agrees that it will provide all documentation reasonably requested by MSD to demonstrate compliance with the Code.
- 36.3 MSD reserves the right, in its sole discretion, to audit the Supplier's operations, books and records to ensure compliance with the Code. MSD will provide reasonable advance notice of such an audit, and may conduct this audit on its own or using a third-party auditor of its choosing. The Supplier shall acknowledge receipt of MSD's notice as promptly as practicable after receipt of such notice and will confirm the date on which the audit will occur within 14 days after receipt of such notice. MSD or its third-party auditor may interview Supplier's employees as part of or in connection with the audit. This audit right shall be in addition to any other audit rights granted in this Agreement.
- 36.4 In the event an audit identifies a non-conformance by the Supplier with the Code, the Supplier will promptly take corrective action to remedy the non-conformance. MSD reserves the right to approve all corrective actions. Corrective actions shall be implemented by the Supplier at the Supplier's expense. MSD will endeavour, whenever practicable, to work with the Supplier to remedy the issue and put in place a corrective action plan.
- 36.5 In the event the Supplier refuses to allow an audit, or fails or refuses to take corrective action, then in addition to any other remedy available to it under this Agreement, at law or in equity, MSD reserves the right to terminate this Agreement in the event the Supplier fails to cure such refusal or failure within 90 days after written notice from MSD.

37. MSD'S SUPPLIER EXPECTATIONS

Without limiting any of the Supplier's other obligations hereunder and without limiting any of the express warranties or obligations agreed to elsewhere in this Agreement, including without limitation its obligations hereof, MSD expects that the Supplier will abide by the letter and spirit of MSD's Supplier Performance Expectations, as in effect from time to time, a copy of which is available at <http://www.msd.com/about/how-we-operate/code-of-conduct/home.html>.